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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,838	02/11/2002	Steven M. Podos	14336	6625

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EXAMINER	
FAY, ZOHREH A	
ART UNIT	PAPER NUMBER

1614
DATE MAILED: 04/04/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/073,838	PODOS ET AL.	
	Examiner Zohreh Fay	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
 - 2a) This action is **FINAL**. 2b) This action is non-final.
 - 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- Disposition of Claims**
- 4) Claim(s) 1-3 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 - 5) Claim(s) _____ is/are allowed.
 - 6) Claim(s) 1-3 is/are rejected.
 - 7) Claim(s) _____ is/are objected to.
 - 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: _____ . |

The reissue oath/declaration filed with this application is defective because it fails to identify at least one error which is relied upon to support the reissue application. See 37 CFR 1.175(a)(1) and MPEP § 1414.

The reissue oath/declaration filed with this application is defective because it fails to contain a statement that all errors which are being corrected in the reissue application up to the time of filing of the oath/declaration arose without any deceptive intention on the part of the applicant. See 37 CFR 1.175 and MPEP § 1414. The reissue declaration fails to contain any real statement of error, and it does not identify specific errors being corrected. Merely mentioning a later issue patent does not identify a specific error.

Claims 1-3 are rejected as being based upon a defective reissue oath/declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention, without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ 1400 (CAFC 1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure

would have required undue experimentation. Citing Ex Parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working example,
- 3) the nature of the invention,
- 4) the state of the prior art,
- 5) the relative skill of those in the art,
- 6) the predictability of the art, and
- 8) the breadth of the claims.

Applicant fails to provide support and examples for the broad phrase of a "cyclic aliphatic aromatic" groups. Additionally applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all "cyclic aliphatic, aromatic" groups, necessitating an exhaustive search for the embodiment suitable to practice the claimed invention. Applicant fails to provide information sufficient to practice the claimed invention, absent undue experimentation.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woodward (U.S. Patent 6,124,353).

Woodward teaches the use of a prostaglandins for the treatment of ocular hypertension. See the abstract. The above reference differs from the claimed invention in the presence of cyclic aliphatic, aromatic ring or the combination of aliphatic and aromatic hydrocarbon at the Z position. It would have been obvious to a person skilled in the art to use the claimed compounds for the treatment of ocular hypertension, considering that Woodward teaches the claimed type compounds have been previously used for the treatment of ocular hypertension. One skilled in the art would have been motivated to employ the teachings of the above reference, since it relates to the use of the claimed type prostglandins for the treatment of ocular hypertension. The substitution of an aliphatic group for a cyclic aliphatic group would have been obvious to a person skilled in the art in the absence of evidence to the contrary. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 1-3 are properly rejected under 35 U.S.C. 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Fay whose telephone number is (703) 308-4604. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone

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numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Z.F
March 28, 2003

